February 2012 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

NEW TESTS Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	**Test Name**	**Effective Date**	**Page #**
90887	**HPV RNA, High Risk, E6/E7, TMA**	3/6/2012	2
9432	***Toxoplasma gondii* IgG Antibodies EIA**	3/13/2012	3
10051	**Hepatitis C Viral RNA,Quan RT-PCR w/Rflx to QL TMA**	4/3/2012	4
948	**Zinc Protoporphyrin (ZPP)**	4/3/2012	4

TEST CHANGES Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.				
Test Code	**Former Test Code**	**Test Name**	**Effective Date**	**Page #**
7468		***Mycobacterium tuberculosis* Complex DNA DetectR™**	2/21/2012	5
5649		**AFB Susceptibility: M. tuberculosis Primary Drugs Susceptibility**	3/6/2012	5
9095		**Heterophile, Mono Screen**	3/6/2012	6
2475		**Rubella Antibody (IgM)**	3/6/2012	6
3258		**CEA**	3/13/2012	6
3123PL		**Cholinesterase, Plasma**	3/13/2012	7
7485A		**HIV-1 RNA Quantitation [Real Time PCR]**	3/13/2012	8
3921		**Testosterone, Total, LC/MS/MS**	3/13/2012	8
2263		***Toxoplasma gondii* IgG & IgM Antibodies**	3/13/2012	8
9426		***Toxoplasma gondii* IgG Abs w/Reflex IgM Abs**	3/13/2012	9
7675		***Toxoplasma gondii* IgM Antibodies EIA**	3/13/2012	9
3140		**C-Peptide**	3/20/2012	10
3145		**C-Peptide (5 Specimens)**	3/20/2012	10
3150		**DHEA-Sulfate**	3/20/2012	11
1160		**Erythropoietin**	3/20/2012	13
3176		**Gastrin**	3/20/2012	13
9861		***Haemophilus influenzae* B IgG Antibodies**	3/20/2012	13
4133U		**Marijuana Metabolite, Quantitation, Urine**	3/20/2012	13
1517		**Haptoglobin**	3/27/2012	14
3184		**Human Chorionic Gonadotropin, Beta**	3/27/2012	14
3206		**Prolactin**	3/27/2012	14
1580		**Protein Electrophoresis (PEP)**	3/27/2012	14
3250		**TSH**	3/27/2012	15
3272		**Erythrocyte Protoporphyrin (EP)**	4/3/2012	15

1331		**Tetanus & Diphtheria Toxoid IgG Antibodies**	4/3/2012	15

DISCONTINUED TESTS **Please Note: Not all test codes assigned to each assay are listed in the table of contents.** **Please refer to the complete listing on the page numbers indicated.**			
Test Code	**Test Name**	**Effective Date**	**Page #**
RI206	**Allergen-Cockroach, American IgE**	3/13/2012	16
3296	**Plasminogen Activator Inhibitor-1**	3/13/2012	16
7666	***Toxoplasma gondii* IgA Antibodies**	3/13/2012	16
2261	***Toxoplasma gondii* IgG, IgM, & IgA Antibodies**	3/13/2012	16
7518	**Hepatitis C Viral RNA, Qualitative w/Rfx Quantitative bDNA**	4/3/2012	16
7476	**Hepatitis C Viral RNA, Quant bDNA w/Reflex Genotype, LIPA**	4/3/2012	17
7576	**Hepatitis C Viral RNA, Quant bDNA w/Reflex Qualitative TMA**	4/3/2012	17
7578	**Hepatitis C Viral RNA, Quant bDNA w/Rfx TMA/Genotype, LIPA**	4/3/2012	17
7486	**Hepatitis C Viral RNA, Quantitative bDNA**	4/3/2012	17
4863	**Lead Whole Blood and Zinc Protoporphyrin**	4/3/2012	17
4863I	**Lead, OSHA Panel with Zinc Protoporphyrin**	4/3/2012	17
3275	**Zinc Protoporphyrin**	4/3/2012	17
3275I	**Zinc Protoporphyrin, Industrial**	4/3/2012	17

SEND OUTS **Please Note: Not all test codes assigned to each assay are listed in the table of contents.** **Please refer to the complete listing on the page numbers indicated.**				
Test Code	**Former Test Code**	**Test Name**	**Effective Date**	**Page #**
S52560		**Cockroach American IgE (19710)**	3/13/2012	18
17086		***Toxoplasma gondii* IgA Antibody, ELISA**	3/13/2012	18
S52568		**Toxoplasmosis Infant/Fetal (<6 months) Panel**	3/13/2012	19
S52569		**Toxoplasmosis Pregnancy Panel (> 16 weeks)**	3/13/2012	20
S52570		**Toxoplasmosis Pregnancy Panel with Avidity (<16 weeks)**	3/13/2012	21

New Test Offerings

The following tests will be available through Quest Diagnostics on the dates indicated below.

HPV RNA, High Risk, E6/E7, TMA	
Clinical Significance	The presence of E6/E7 messenger RNA from 14 high risk HPV types indicates incorporation of HPV DNA into the host cells. Proteins expressed from E6-E7 polycistronic mRNA alter cellular p53 and retinoblastoma protein functions, leading to disruption of cell-cycle check points and cell genome instability. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.
Effective Date	**3/6/2012**

Test Code	**90887**
CPT Codes	**87621**
Specimen Requirements	**ThinPrep® vial with 3 mL Residual PreservCyt® Fluid** **1. Collect cervical specimens in ThinPrep® Pap Test vials containing PreservCyt® Solution with broom-type or cytobrush/spatula collection devices according to the manufacturer's instructions.** **2. Alternatively, 2 mL PreservCyt® can be aliquoted pre-cytology.**
Reject Criteria	**Cervical swabs in Digene HC Cervical Sampler; Digene vials; Vaginal swabs; SurePath vials**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 30 days** **Refrigerated: 90 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Tue, Fri; Report available: 3-5 days**
Reference Range	**Not Detected**
Methodology	**Transcription Mediated Amplification (TMA)**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code** / **Result Name** **86008309** / **HPV RNA,HighRisk,E6/E7,TMA**

***Toxoplasma gondii* IgG Antibodies EIA**	
Clinical Significance	**Toxoplasmosis is caused by infection by the parasite Toxoplasma gondii. Approximately 23% of the population carry the parasite but remain healthy while not immunocompromised. Transmission from a pregnant woman to her fetus can cause serious disease. A high Antibody IgG and Antibody IgM together support infection within the previous three months. A high Antibody IgG with a low-to-medium Antibody IgM together support infection within three to six months.**
Effective Date	**3/13/2012**
Test Code	**9432**
CPT Codes	**86777**
Specimen Requirements	**1.0 mL (0.3 mL) Serum**
Specimen Stability	**Room temperature: 4 days** **Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Tue, Thu, Sat; Report available: 1-4 days**
Reference Range	**< .91 Index**
Always Message	**REFERENCE RANGE for Toxoplasma gondii IgG Abs:** **Less than 0.91 Index . . . . Negative** **0.91 - 1.09 Index . . . . . Equivocal** **Greater than 1.09 Index . . . Positive** **A positive result indicates that the patient has antibody to Toxoplasma IgG. It does not differentiate between an active or past infection. The clinical diagnosis must be interpreted in conjunction with the clinical signs and symptoms of the patient.**
Methodology	**EIA**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**

CPU Mappings	

Result Code	Result Name
211415	Toxoplasma gondii IgG Abs

Hepatitis C Viral RNA,Quan RT-PCR w/Rflx to QL TMA	
Message	**Replacement for test code 7576 Hepatitis C Viral RNA, Quant bDNA w/Reflex Qualitative TMA**
Effective Date	**4/3/2012**
Test Code	**10051**
CPT Codes	**87522**
Specimen Requirements	**5.0 mL (3.0 mL) Plasma collected in two EDTA (lavender-top) tubes** **Alternates:** **5.0 mL (3.0 mL) Plasma collected in a PPT Potassium EDTA (white top)** **5.0 mL (3.0 mL) Serum Red-top tube (no gel)**
Reject Criteria	**Unspun PPT tube, Received room temperature, Samples collected using heparin as anticoagulant**
Instructions	**If HCV RNA, Quantitative, is < 43 IU/mL, test will reflex to HCV RNA Qualitative, TMA (CPT: 87521) at an additional charge. 5 mL plasma collected in two EDTA lavender-top tubes. Separate plasma from whole blood within 6 hours of collection by centrifugation at 800 to 1600 x g for 20 minutes at room temperature (Minimum: 3 mL). Transfer the plasma to a properly identified, sterile, polypropylene screw-capped vial (s), freeze, and ship frozen.**
Transport Temperature	**Frozen**
Specimen Stability	**Room Temperature: unacceptable** **Refrigerated: 72 hours** **Frozen: 42 days**
Set-up/Analytic Time	**Set up: Tues-Sat; Report available: 3-7 days**
Reference Range	

HCV RNA, PCR, Quant	**<43 IU/mL**
HCV RNA, PCR, Quant	**<1.63 LogIU/mL**

Always Message	**Please note: the guidelines for the use of new anti-HCV therapies (boceprevir and telaprevir) recommend using a test method that detects plasma viral nucleic acid levels as low as 10 IU/ml. This assay has a lower Limit of Detection of 7.1 IU/ml for genotype 1 and conforms to the recommendation. Quantitation of plasma HCV nucleic acid levels below 43 IU/ml (the lower Limit of Quantitation for this test) may not be linear, and in this circumstance are reported as <43 IU/mL HCV RNA Detected.** **This test was performed using the COBAS(® AmpliPrep / COBAS® TaqMan® HCV Test Kit (Roche Molecular Systems, Inc.**
Methodology	**Real-Time PCR**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code:	Result Name:
55194255	**HCV RNA (IU/ML)**
55194250	**HCV RNA (LOG IU/ML)**
REFLEX ROG	
85992668	**HCV RNA, QUAL., TMA**

Additional Information	**Linear range: 43-69,000,000 IU/mL**

Zinc Protoporphyrin (ZPP)	
Message	Replacement for test code 3275I
Clinical Significance	**Zinc protoporphyrin (ZPP) accumulates in erythrocytes as a result of chronic lead absorption or iron deficiency anemia.**
Effective Date	**4/3/2012**
Test Code	**948**
CPT Codes	**84202**
Specimen Requirements	**2 mL (0.5 mL) whole blood collected in EDTA (lavender-top) tube.** **Alternates:** **2 mL (0.5 mL) whole blood collected in EDTA (royal blue) tube.** **2 mL (0.5 mL) whole blood collected in EDTA (green top sodium heparin) tube.** **2 mL (0.5 mL) whole blood collected in EDTA (tan top sodium heparin) tube.** **Specimen should be foil wrapped. Protect from light. Use a lead free tube if blood lead is also requested.**
Reject Criteria	**Frozen, clotted, or hemolyzed**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 4 days** **Refrigerated: 10 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Sun-Sat; Report available: 2 days**
Reference Range	**Industrial Exposure < 100**
Units Of Measure	mcg/dL
Methodology	**Fluorometry**
Assay Category	**Laboratory Developed Test**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
CPU Mappings	**Result Code** / **Result Name** **50055300** / **Zinc Protoporphyrin (ZPP)**

Test Changes

The following test changes will be effective on the dates indicated below. **Please note that only the fields listed in bold type are being changed; former test names and test codes have been italicized.** Additional information, regarding the change, will be provided where applicable.

***Mycobacterium tuberculosis* Complex DNA DetectR™**	
Effective Date	**2/21/2012**
Test Code	7468
Always Message	**This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test.**
Assay Category	**Laboratory Developed Test**

AFB Susceptibility: M. tuberculosis Primary Drugs Susceptibility

Effective Date	**3/6/2012**
Former Test Name	*AFB Suscept: M. tuberculosis Primary Drugs Radiometric Panel*
Test Code	5649
Additional Information	1. Send PURE culture only. If the specimen is mixed, there will be no work up pending clarification with the client. There will be separate charges for each organism that requires susceptibility testing. 2. If broth submitted is mixed with other Mycobacterium species or non-acid fast bacteria, it will be subbed onto an agar plate for isolation. This will delay test results. 3. If M. tuberculosis is resistant to one or more primary drugs, it is confirmed by agar proportion method, AFB Susceptibility: Mycobacterium spp., test code #5653 at an additional charge. Add 2-5 days to turnaround time. **4. Primary drugs tested: Streptomycin 1.0 ug/mL; Isoniazid 0.1 ug/mL; Rifampin 1.0 ug/mL; Ethambutol 5.0 ug/mL; Pyrazinamide 100.0 ug/mL; Results are reported as: S for Sensitive - R for Resistant** 5. Primary susceptibility testing is automatically performed on all M. tuberculosis isolated from cultures. CPT Codes: 87190x5

Heterophile, Mono Screen	
Effective Date	**3/6/2012**
Former Test Name	*Heterophile Agglutination*
Test Code	9095
Reject Criteria	**Gross hemolysis or gross lipemia is unacceptable.**
Transport Temperature	Room Temperature
Specimen Stability	**Room Temperature: 4 days** **Refrigerated: 7 days** **Frozen: 30 days**
Reference Range	**Negative**
Methodology	**Latex Agglutination**
CPU Mappings	**Result Code** / **Result Name**: 28121 / **Heterophile, Mono Screen**
Additional Information	**Also known as Mononucleosis Screen, Monospot, Mono Test, Heterophile**.

Rubella Antibody (IgM)	
Clinical Significance	**Rubella is an acute exanthematous viral infection of children and adults. Rash, fever, and lymphadenopathy characterize the illness. While many infections are subclinical, this virus has the potential to cause fetal infection with resultant birth defects. In the absence of a current or recent infection, a demonstration of specific IgG on a serum sample is evidence of immunity to Rubella. A positive Rubella IgM result does not necessarily indicate current or recent infection. Without a history of exposure to Rubella or symptoms consistent with Rubella, the IgM result may be difficult to interpret. Rubella IgM can be false positive due to other causes (e.g., Parvovirus, Rheumatoid Factor, Cytomegalovirus). Rubella IgM may also persist for more than 12 months after vaccination or natural infection. For a serologic diagnosis of congenital Rubella in the neonatal period, antibody to Rubella virus should be measured in both infant and maternal sera. If IgM is detected in a newborn infant's serum, it is probable that transplacental Rubella infection has occurred.**
Effective Date	**3/6/2012**
Test Code	2475
Specimen Requirements	1.0 mL **(0.6 mL)** Serum
Always Message	**A positive Rubella IgM result does not necessarily indicate current or recent infection. Without a history of exposure to Rubella or symptoms consistent with Rubella, the IgM result may be difficult to interpret. Rubella IgM can be false positive, due to other causes (e.g., Parvovirus, Rheumatoid Factor, Cytomegalovirus). Rubella IgM may also persist for more than 12 months after vaccination or natural infection. Rubella IgM serology should not be ordered for routine prenatal care; instead, Rubella IgG**

	should be ordered.

CEA	
Clinical Significance	**Increased serum CEA levels have been detected in persons with primary colorectal cancer and in patients with other malignancies involving the gastrointestinal tract, breast, lung, ovarian, prostatic, liver, and pancreatic cancers. Elevated serum CEA levels have also been detected in patients with nonmalignant disease, especially patients who are older or who are smokers. CEA levels are not useful in screening the general population for undetected cancers. However, CEA levels provide important information about patient prognosis, recurrence of tumors after surgical removal, and effectiveness of therapy. See Carcinoembryonic Antigen (CEA) in the Hematology/Oncology chapter, Interpretive Information section.**
Effective Date	**3/13/2012**
Former Test Name	*Carcinoembryonic Antigen (CEA)*
Test Code	3258
Specimen Requirements	**1.0 mL (0.5 mL)** Serum
Transport Temperature	**Room temperature**
Specimen Stability	**Room Temperature: 7 days** **Refrigerated: 30 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon-Sun; Report available: 1-2 days**
Reference Range	**0.0-2.4 ng/mL** **Nonsmokers: < 2.5 ng/mL** **Smokers: < 5.0 ng/mL**
Always Message	**This test was performed using the Siemens chemiluminescent method. Values obtained from different assay methods cannot be used interchangeably. CEA levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of disease.**
Methodology	**Immunoassay**
Additional Information	**Remove references to CEA, CSF and CEA, Fluid from Notes sections as listed tests are no longer orderable.**
Tests Affected	**Test Codes:** / **Name:** 3258SR — Carcinoembryonic Antigen with serial reporting 3024 — Colorectal Cancer Monitor 3254 — Small-Cell Carcinoma Monitor, Lung

Cholinesterase, Plasma	
Clinical Significance	**Approximately 1 in every 2500 individuals has inherited defective or deficiency of the enzyme (pseudocholinesterase) that metabolizes succinylcholine (an anesthetic agent). With normal dosage, these individuals have prolonged apnea. Such individuals are responsive at much smaller concentrations of this anesthetic agent than the general population. Low concentrations of pseudocholinesterase are observed in individuals exposed to organophosphorous insecticides and patients with hepatic dysfunction.**
Effective Date	**3/13/2012**
Test Code	3123PL
Specimen Requirements	**1 mL (0.5 mL)** Plasma
Instructions	**Instructions: Draw a lavender-top (EDTA) tube of whole blood. Spin tube to separate plasma. Pour plasma into plastic aliquot tube and refrigerate until shipping. Ship plasma sample refrigerated. Do not send**

	packed cells. Do not send one tube of whole blood. Plasma cholinesterase results are not accurate if plasma sample is not separated from RBC's in a timely manner (within 1 hr). Hemolyzed plasma samples are not acceptable. Hemolysis can lead to apparent increases in plasma cholinesterase activity, and could mask an enzyme deficiency. Centrifuge and transfer plasma specimens to clean, plastic, screw-capped vial(s).
Transport Temperature	**Refrigerated**
Specimen Stability	**Room Temperature: 21 days** **Refrigerated: 21 days** **Frozen: 30 days**
Methodology	**Kinetic** **Spectrophotometric**
Tests Affected	**Test Codes:** / **Name:** 3123PLSR / Cholinesterase Plasma with serial reporting

HIV-1 RNA Quantitation [Real Time PCR]	
Effective Date	**3/13/2012**
Test Code	7485A
Set-up/Analytic Time	**Set up: Tue-Sat**; Report available: 3-4 days
Tests Affected	**Test Codes:** / **Name:** 7485ASR / HIV-1 RNA Quantitation [Real Time PCR] with serial reporting

Testosterone, Total, LC/MS/MS	
Effective Date	**3/13/2012**
Test Code	3921
Reference Range	**Males** / **> or = 18 years** / **250-1100** / **ng/dL** **Females** / **> or = 18 years** / **2- 45** / **ng/dL**
Tests Affected	**Test Codes:** / **Name:** 36170 / Testosterone, Free and Total, LC/MS/MS 3201 / Testosterone, Free LC/MS/MS 3922 / Testosterone, Free and Total, LC/MS/MS 3924 / Testosterone, Free, Bioavailable and Total LC/MS/MS 3231 / Testosterone, Free, Total, and Sex Hormone Binding Globulin 14966X / Testosterone, Free, Bioavailable and Total, LC/MS/MS 15983 / Testosterone, Total LC/MS/MS 90572 / Testosterone, Free, LC/MS/MS

***Toxoplasma gondii* IgG & IgM Antibodies**

Clinical Significance	**Toxoplasmosis is caused by infection by the parasite Toxoplasma gondii. Approximately 23% of the population carry the parasite but remain healthy while not immunocompromised. Transmission from a pregnant woman to her fetus can cause serious disease. A high Antibody IgG and Antibody IgM together support infection within the previous three months. A high Antibody IgG with a low-to-medium Antibody IgM together support infection within three to six months.**
Effective Date	**3/13/2012**
Test Code	2263
Specimen Requirements	1.0 mL **(0.3 mL)** Serum
Specimen Stability	**Room temperature: 4 days** **Refrigerated: 7 days** **Frozen: 30 days**
Always Message	**Added:** **A positive result indicates that the patient has antibody to Toxoplasma IgG. It does not differentiate between an active or past infection. The clinical diagnosis must be interpreted in conjunction with the clinical signs and symptoms of the patient.** **Possible acute infection or false positive IgM result. Consider obtaining a new specimen for IgG and IgM testing. If results from the second specimen remain the same, the IgM reaction is probably a false-positive. Physicians are advised to interpret the results of anti-Toxoplasma IgM tests with caution, and should not rely on any single test result as the sole determinant in diagnosing recently acquired infection.** **Follow-up testing can be performed at Palo Alto Medical Foundation. Please call client services to order one of the following panels, as appropriate:** **Test Code S52568: Toxoplasmosis infant/fetal(<6months)** **Test Code S52569: Pregnant females over 16 weeks gestation** **Test Code S52570: Pregnant females under 16 weeks gestation**
Tests Affected	**Test Codes:** / **Name:** 9901 / TORCH IgG & IgM Antibodies Evaluation

***Toxoplasma gondii* IgG Abs w/Reflex IgM Abs**	
Clinical Significance	**Toxoplasmosis is caused by infection by the parasite Toxoplasma gondii. Approximately 23% of the population carry the parasite but remain healthy while not immunocompromised. Transmission from a pregnant woman to her fetus can cause serious disease. A high Antibody IgG and Antibody IgM together support infection within the previous three months. A high Antibody IgG with a low-to-medium Antibody IgM together support infection within three to six months.**
Effective Date	**3/13/2012**
Test Code	9426
Specimen Requirements	1.0 mL **(0.3 mL)** Serum
Specimen Stability	**Room temperature: 4 days** **Refrigerated: 7 days** **Frozen: 30 days**
Always Message	**Added:** **A positive result indicates that the patient has antibody to Toxoplasma IgG. It does not differentiate between an active or past infection. The clinical diagnosis must be interpreted in conjunction with the clinical signs and symptoms of the patient.**
Tests Affected	**Test Codes:** / **Name:** 9911 / TORCH IgG Antibodies Evaluation

***Toxoplasma gondii* IgM Antibodies EIA**	
Clinical Significance	**Toxoplasmosis is caused by infection by the parasite Toxoplasma gondii. Approximately 23% of the population carry the parasite but remain healthy while not immunocompromised. Transmission from a pregnant woman to her fetus can cause serious disease. A high Antibody IgG and Antibody IgM together support infection within the previous three months. A high Antibody IgG with a low-to-medium Antibody IgM together support infection within three to six months.**
Effective Date	**3/13/2012**
Test Code	7675
Specimen Requirements	1.0 mL **(0.3 mL)** Serum
Specimen Stability	**Room temperature: 4 days** **Refrigerated: 7 days** **Frozen: 30 days**
Always Message	**Possible acute infection or false positive IgM result. Consider obtaining a new specimen for IgG and IgM testing. If results from the second specimen remain the same, the IgM reaction is probably a false-positive. Physicians are advised to interpret the results of anti-Toxoplasma IgM tests with caution, and should not rely on any single test result as the sole determinant in diagnosing recently acquired infection.** **Follow-up testing can be performed at Palo Alto Medical Foundation. Please call client services to order one of the following panels, as appropriate:** **Test Code S52568: Toxoplasmosis infant/fetal(<6months)** **Test Code S52569: Pregnant females over 16 weeks gestation** **Test Code S52570: Pregnant females under 16 weeks gestation**
Tests Affected	**Test Codes:** / **Name:** 7675C / Toxoplasma gondii IgM Antibodies CSF RGA / Reflex Toxoplasma gondii IgM Abs EIA

C-Peptide	
Clinical Significance	**C-Peptide is useful in the evaluation of pancreatic beta cell function and for determining the source of insulin in patients with hyperinsulinemic hypoglycemia**.
Effective Date	**3/20/2012**
Test Code	3140
Specimen Requirements	**1.0 mL (0.4 mL) Frozen Serum** **Alternate:** **Refrigerated serum (within stability)** **Frozen sodium heparin (green-top tube) plasma** **Refrigerated sodium heparin (green-top tube) plasma (within stability)**
Reject Criteria	**Room temperature samples received more than 24 hours after collection.**
Instructions	**Fasting specimen**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: 24 hours** **Refrigerated: 7 days** **Frozen -20° C: 28 days** **Frozen -70° C: 12 months**
Set-up/Analytic Time	**Set Up: Mon-Fri; Report available: 1-2 days**

Methodology	**Immunoassay**

C-Peptide (5 Specimens)	
Clinical Significance	**C-Peptide is useful in the evaluation of pancreatic beta cell function and for determining the source of insulin in patients with hyperinsulinemic hypoglycemia**.
Effective Date	**3/20/2012**
Test Code	3145
Specimen Requirements	**1.0 mL (0.4 mL) Frozen Serum** **Alternate:** **Refrigerated serum (within stability)** **Frozen sodium heparin (green-top tube) plasma** **Refrigerated sodium heparin (green-top tube) plasma (within stability)**
Reject Criteria	**Room temperature samples received more than 24 hours after collection.**
Instructions	**Fasting specimen**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: 24 hours** **Refrigerated: 7 days** **Frozen -20° C: 28 days** **Frozen -70° C: 12 months**
Set-up/Analytic Time	**Set Up: Mon-Fri; Report available: 1-2 days**
Reference Range	Fasting 0.80-3.10 ng/mL **30 min 2.10-10.80 ng/mL** **60 min 2.30-11.90 ng/mL** **90 min 1.70-11.50 ng/mL** **120 min 1.20-8.60 ng/mL**
Methodology	**Immunoassay**

DHEA-Sulfate	
Clinical Significance	**DHEA-S is the sulfated form of DHEA and is the major androgen produced by the adrenal glands. This test is used in the differential diagnosis of hirsute or virilized female patients and for the diagnosis of isolated premature adrenarche and adrenal tumors. About 10% of hirsute women with polycystic ovarian syndrome (PCOS) have elevated DHEA-S, but normal levels of other androgens.**
Effective Date	**3/20/2012**
Test Code	3150
Specimen Requirements	1.0 mL (0.5 mL) Serum
Transport Temperature	**Refrigerated**
Specimen Stability	**Room Temperature: 3 days** **Refrigerated: 7 days** **Frozen: 28 days**
Reference Range	**DHEA-S, Females**

Age	**Range**
< 1 month	**15-261 mcg/dL**
1-6 months	**< or = 74 mcg/dL**
7-11 months	**< or = 26 mcg/dL**
1-3 yrs	**< or = 22 mcg/dL**

4-6 yrs	**< or = 34 mcg/dL**
7-9 yrs	**< or = 92 mcg/dL**
10-13 years	**< or = 148 mcg/dL**
14-17 years	**37-307 mcg/dL**
Tanner Stages (7-17 years)	
Tanner I	**< or = 46 mcg/dL**
Tanner II	**15-113 mcg/dL**
Tanner III	**42-162 mcg/dL**
Tanner IV	**42-241 mcg/dL**
Tanner V	**45-320 mcg/dL**
18-29 years	**45-320 mcg/dL**
30-39 years	**40-325 mcg/dL**
40-49 years	**25-220 mcg/dL**
50-59 years	**15-170 mcg/dL**
60-69 years	**< or = 185 mcg/dL**
70-90 years	**< or = 90 mcg/dL**
> 90 years	**Not Established**

DHEA-S, Males

Age	Range
< 1 month	**< or = 316 mcg/dL**
1-6 months	**< or = 58 mcg/dL**
7-11 months	**< or = 26 mcg/dL**
1-3 yrs	**< or = 15 mcg/dL**
4-6 yrs	**< or = 27 mcg/dL**
7-9 yrs	**< or = 91 mcg/dL**
10-13 years	**< or = 138 mcg/dL**
14-17 years	**38-340 mcg/dL**
Tanner Stages (7-17 years)	
Tanner I	**< or = 89 mcg/dL**
Tanner II	**< or = 81 mcg/dL**
Tanner III	**22-126 mcg/dL**
Tanner IV	**33-177 mcg/dL**
Tanner V	**110-510 mcg/dL**
18-29 years	**110-510 mcg/dL**
30-39 years	**110-370 mcg/dL**

	40-49 years — **45-345 mcg/dL** **50-59 years** — **25-240 mcg/dL** **60-69 years** — **25-95 mcg/dL** **70-90 years** — **< or = 75 mcg/dL** **> 90 years** — **Not Established**
Units Of Measure	**mcg/dL**
Methodology	**Immunoassay**
Tests Affected	**Test Codes:** / **Name:** 2016 — Infertility: Endocrine Evaluation (Female)

Erythropoietin	
Effective Date	**3/20/2012**
Test Code	1160
Instructions	**Remove:** Please number each specimen in sequence and label with the collection time. Transfer serum to 5 separate, plastic, screw-capped vials (1 mL EACH). Transport at room temperature in the same shipping container.
Transport Temperature	**Room temperature**

Gastrin	
Effective Date	**3/20/2012**
Test Code	3176
Reject Criteria	**Grossly hemolyzed specimens**

***Haemophilus influenzae* B IgG Antibodies**	
Effective Date	**3/20/2012**
Test Code	9861
Reject Criteria	**Grossly hemolyzed, grossly icteric, or grossly lipemic samples**
Tests Affected	**Test Codes:** / **Name:** 9861P — Haemophilus influenzae B IgG Antibodies, Pre/Post Vaccination

Marijuana Metabolite, Quantitation, Urine	
Effective Date	**3/20/2012**
Former Test Name	*Cannabinoids Confirmation Urine*
Test Code	4133U
Specimen Stability	**Room Temperature: 5 days** **Refrigerated: 7 days** **Frozen: 30 days**

CPU Mappings	**Result Code** / **Result Name** 200782 / **Marijuana Metabolite**
Tests Affected	**Test Codes:** / **Name:** RKS / Reflex Cannabinoids Confirmation Urine

Haptoglobin	
Clinical Significance	**Decreased haptoglobin is found in hemolytic disease, hepatocellular disease and infectious mononucleosis. Increased level is found in inflammatory disease in the presence of tissue necrosis and in general acute inflammatory conditions.**
Effective Date	**3/27/2012**
Test Code	1517
Instructions	**CSF is an unacceptable sample type for this test.** **Overnight fasting is preferred.**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 48 hours** **Refrigerated: 7 days** **Frozen: 90 days**
Reference Range	**Adults: 43-212 mg/dL**

Human Chorionic Gonadotropin, Beta	
Effective Date	**3/27/2012**
Test Code	3184
Always Message	**Quantitation of HCG is done by Immunochemiluminometric Assay on the Beckman-Coulter DXI-800. Values from different assay methods may vary. The use of this assay to monitor or to diagnose patients with cancer or any condition other than pregnancy has not been approved by the FDA or the manufacturer of the assay.** **Women with hCG values between 5 and 25 mIU/mL should have the result confirmed by repeat analysis in two to four days if clinically indicated.**
Tests Affected	**Test Codes:** / **Name:** 3184SR / Human Chorionic Gonadotropin, Beta with serial reporting 3028 / Alpha-Fetoprotein & Human Chorionic Gonadotropin 3028SR / Alpha-Fetoprotein & Human Chorionic Gonadotropin with serial reporting

Prolactin	
Effective Date	**3/27/2012**
Test Code	3206
Instructions	Collect 3-4 hours after patient has awakened. **Overnight fasting is preferred.**
Tests Affected	**Test Codes:** / **Name:**

2016	Infertility: Endocrine Evaluation (Female)

Protein Electrophoresis (PEP)	
Effective Date	**3/27/2012**
Test Code	1580
Reject Criteria	Hemolysis and **lipemic** specimens
Tests Affected	

Test Codes:	**Name:**
1580G	Protein Electrophoresis (PEP) with Scan
1583	Protein Electrophoresis (PEP) with Monoclonal Region
1583G	Protein Electrophoresis (PEP) with Monoclonal Region with Scan
1584	Protein Electrophoresis (PEP) Evaluation Serum

TSH	
Effective Date	**3/27/2012**
Former Test Name	*TSH, 3rd Generation*
Test Code	3250
Additional Information	**Name change only - remove 3rd Generation**
Tests Affected	

Test Codes:	**Name:**
3250SR	Thyroid Stimulating Hormone, 3rd Generation with serial reporting
3060	Thyroid Antibodies Evaluation
3072	Thyroid Panel, Hyperthyroidism
1091	Thyroid Stimulating Immunoglobulins with TSH
1090	Thyrotropin Receptor Autoantibody with TSH
3074	Thyroid Panel, Hypothyroidism

Erythrocyte Protoporphyrin (EP)	
Clinical Significance	**Erythrocyte Protoporphyrin (EP) testing is used by the clinician to assist with detection and diagnosis of iron deficiency anemia, iron deficiency without anemia, and inflammatory conditions that impact heme synthesis and porphyrinopathies.**
Effective Date	**4/3/2012**
Former Test Name	*Erythrocyte Protoporphyrin*
Test Code	3272
Specimen Stability	**Room Temperature: 5 days** **Refrigerated: 30 days** **Frozen: unacceptable**
Reference Range	**< 70 umol/mol heme**
Units Of Measure	**umol/mol heme**

Methodology	**Fluorometric**

Tetanus & Diphtheria Toxoid IgG Antibodies	
Effective Date	**4/3/2012**
Test Code	1331
Reject Criteria	**Grossly hemolyzed, grossly lipemic, or grossly icteric specimens**
Tests Affected	

Test Codes:	**Name:**
1331P	Tetanus & Diphtheria Toxoid IgG Antibodies, Pre/Post Vaccination
1334	Tetanus Toxoid IgG Antibodies
1334P	Tetanus Toxoid IgG Antibodies, Pre/Post Vaccination

Discontinued Tests

Allergen-Cockroach, American IgE	
Message	Suggested replacement test code S52560 Allergen - Cockroach American IgE (190710)
Effective Date	**3/13/2012**
Test Code	RI206
Tests Affected	

Test Codes:	**Name:**
3800	Region 1 Allergy Profile

Plasminogen Activator Inhibitor-1	
Message	Suggested replacement test code S52559 Plasminogen Activator Inhibitor (PAI-1) Antigen [36555X]
Effective Date	**3/13/2012**
Test Code	3296
Tests Affected	

Test Codes:	**Name:**
5991	Cardiovascular Thrombotic Risk AssessR™
5973	Thrombotic Risk Evaluation 3

***Toxoplasma gondii* IgA Antibodies**	
Message	Suggested replacement test code 17086 Toxoplasma gondii IgA Antibody, ELISA
Effective Date	**3/13/2012**
Test Code	7666

***Toxoplasma gondii* IgG, IgM, & IgA Antibodies**	
Message	Suggested replacement test codes 2263*Toxoplasma gondii* IgG & IgM Abs and 17086*Toxoplasma gondii* IgA Antibody, ELISA.

Effective Date	**3/13/2012**
Test Code	2261

Hepatitis C Viral RNA, Qualitative w/Rfx Quantitative bDNA	
Message	Recommended replacement test codes 7577 HCV RNA, Quantitative Real-Time PCR or 7516 Hepatitis C Viral RNA, Qualitative TMA
Effective Date	**4/3/2012**
Test Code	7518

Hepatitis C Viral RNA, Quant bDNA w/Reflex Genotype, LIPA	
Message	Suggested replacement test code 7489 HCV RNA, QUANTITATIVE PCR W/REFLEX GENOTYPE, LIPA
Effective Date	**4/3/2012**
Test Code	7476

Hepatitis C Viral RNA, Quant bDNA w/Reflex Qualitative TMA	
Message	Suggested replacement test code 10051 HCV RNA, Quantitative Real-Time PCR
Effective Date	**4/3/2012**
Test Code	7576

Hepatitis C Viral RNA, Quant bDNA w/Rfx TMA/Genotype, LIPA	
Message	Recommended replacement test code 7489 HCV RNA, Quantitative PCR w/Reflex Genotype, LIPA
Effective Date	**4/3/2012**
Test Code	7578

Hepatitis C Viral RNA, Quantitative bDNA	
Message	Suggested replacement test code 7577 HCV RNA, QUANTITATIVE REAL-TIME PCR
Effective Date	**4/3/2012**
Test Code	7486

Lead Whole Blood and Zinc Protoporphyrin	
Message	Suggested replacement test codes 4861W Lead Whole Blood and 3272 Erythrocyte Protoporphyrin
Effective Date	**4/3/2012**
Test Code	4863

Lead, OSHA Panel with Zinc Protoporphyrin	
Message	Suggested replacement test codes 4861I Lead Whole Blood, Industrial - OSHA and 948 Zinc Protoporphyrin (ZPP)
Effective Date	**4/3/2012**
Test Code	4863I

Zinc Protoporphyrin	
Message	Suggested replacement test code 3272 Erythrocyte Protoporphyrin

Effective Date	**4/3/2012**
Test Code	3275

Zinc Protoporphyrin, Industrial	
Message	Suggested replacement test code 948 Zinc Protoporphyrin (ZPP)
Effective Date	**4/3/2012**
Test Code	3275I

Referral Tests

Due to these assays being performed by outside vendors, we are unable to use our normal method of communication. Some of the changes listed in this document may be effective in less than 30 days. Please note the individual effective dates below, as these changes may require **IMMEDIATE ACTION.**

The following tests will be available through Quest Diagnostics on the dates indicated below.

Cockroach American IgE (19710)	
Message	Replacement for test code RI206
Effective Date	**3/13/2012**
Test Code	S52560
CPT Codes	86001
Specimen Requirements	0.5 mL (0.3 mL) Serum
Transport Temperature	Room temperature
Specimen Stability	Room temperature: 14 days Refrigerated: 30 days Frozen: 30 days
Set-up/Analytic Time	Set up: Mon-Fri; Report available: 3-4 days
Units Of Measure	ku/L
Always Message	This conventional RAST uses allergen-coated discs from several suppliers and an isotope-labeled anti-IgE from Hycor Biomedical. The test was developed and its performance characteristics determined by Viracor-IBT Laboratories. It has not been cleared or approved by FDA. According to CLIA regulations, this test can be used for clinical purposes and should not be regarded as investigational or for research. IgE CONC (kU/L) CLASS INTERPRETATION <0.1 0 Below Detection 0.10-0.34 0/1 Equivocal/Borderline 0.35-0.69 1 Low Positive 0.70-3.4 2 Moderate Positive 3.5-17.4 3 Positive >17.4 4 Strong Positive
Methodology	RIA
Assay Category	Laboratory Developed Test
Performing Site	Viracor-IBT Laboratories, Inc.
CPU Mappings	**Result Code** / **Result Name** 113743 / Cockroach American IgE

	113744 Class

***Toxoplasma gondii* IgA Antibody, ELISA**	
Message	******This test is not approved for New York patient testing***.*** **Replacement for test code 7666 *Toxoplasma gondii* IgA Antibodies**
Clinical Significance	**IgA antibodies against *Toxoplasma gondii* have been detected in acute toxoplasmosis, but not in cases of chronic toxoplasmosis or in uninfected individuals. *T gondii* IgA is thus a valuable tool for the early detection of acute disease in pregnant women and individuals with AIDS. Because IgA antibodies do not cross the placenta, assessment of IgA antibodies against *T. gondii* is also a reliable method for detecting congenital *T. gondii* infection.**
Effective Date	**3/13/2012**
Test Code	17086
CPT Codes	**86777**
Specimen Requirements	**1 mL (0.1 mL) Serum Serum Separator Tube**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room Temperature: 1 week** **Refrigerated: 2 months** **Frozen: 1 year**
Set-up/Analytic Time	**Set up: Tues, Fri; Report available: 3 days**
Reference Range	**<0.90**
Always Message	**Interpretive Criteria:** **<0.90** — **Antibody Not Detected** **0.9 - 1.09** — **Equivocal** **> or = 1.10** — **Antibody Detected** **IgA antibodies against *Toxoplasma gondii* have been detected in acute toxoplasmosis, but not in cases of chronic toxoplasmosis or in uninfected individuals. *T gondii* IgA is thus a valuable tool for the early detection of acute disease in pregnant women and individuals with AIDS. Because IgA antibodies do not cross the placenta, assessment of IgA antibodies against *T. gondii* is also a reliable method for detecting congenital *T. gondii* infection.**
Methodology	**ELISA**
Assay Category	**FDA Approved**
Performing Site	**Focus Diagnostics, Inc.**
CPU Mappings	**Result Code**: **86005572** — **Result Name**: **Toxoplasma gondii IgA, ELISA**

Toxoplasmosis Infant/Fetal (<6 months) Panel	
Effective Date	**3/13/2012**
Test Code	S52568
CPT Codes	86777, 86778,86777-59
Specimen Requirements	2.0 mL (0.5 mL) Serum Red Top Tube

Reject Criteria	ICTERIC, HEMOLYSIS , LIPEMIC, BACTERIALLY CONTAMINATED SPECIMENS
Instructions	INCLUDE PATIENT'S DATE OF BIRTH ON TEST REQUEST FORM. PLEASE CENTRIFUGE THE SPECIMEN. SEND SERUM ONLY. THE PATIENT'S NAME AND COLLECTION DATE MUST APPEAR ON THE SPECIMEN LABEL. UNLABELED SPECIMENS WILL NOT BE TESTED. HISTORY OF PATIENT IS REQUIRED FOR THE PROPER INTERPRETATION OF RESULTS. SUBMIT ALONG WITH THE SPECIMEN ANY HISTORY OF THE FOLLOWING: EYE FINDINGS; NORMAL NEUROLOGICAL FINDINGS; NORMAL BRAIN CALCIFICATION; ULTRASOUND; CT SCAN; TRANSFUSION HISTORY (DATES AND TYPES); HYDROCEPHALY (VENTRICULOMEGALY); CEREBRAL SPINAL FLUID RESULTS: CELL COUNT; GLUCOSE; PROTEIN. IT IS SUGGESTED THAT A MATERNAL SERUM SPECIMEN BE SUBMITTED ALONG WITH THE INFANT SPECIMEN SHOULD ADDITIONAL TESTING BE REQUIRED. THIS WILL BE PERFORMED AT AN ADDITIONAL CHARGE. CONTACT CLIENT SERVICES FOR CHARGES.
Transport Temperature	Room temperature
Specimen Stability	Room Temperature: 7 days Refrigerated: 14 days Frozen: Indefinitely
Set-up/Analytic Time	Set up: Tue, Thur; Report Available: 2-3 days
Reference Range	See laboratory report
Always Message	If you have questions regarding these results, please telephone our consulting physicians at (650) 853-4828. The Sabin-Feldman Dye Test: measures primarily IgG antibodies. Any titer is considered positive. Serum is tested at a 1:16 dilution unless we are notified that patient has eye disease, in which case serum is tested undiluted. IgM-ISAGA: IgM-ISAGA is highly sensitive and is recommended for infants in whom congenital toxoplasmosis is suspected. False positive results in adults may occur. IgA-ELISA: (adults) negative 0.0-1.4, equivocal 1.5-2.0, positive >=2.1; (infants < 6 months) negative 0.0-0.9, positive >=1.0. The IgA-ELISA appears to be a more sensitive test for detection of infection in the fetus and newborn than IgM. Both tests should be performed. If the IgA result on serum obtained within the first days of life is positive, the test should be repeated on serum collection ten days after birth to exclude the possibility that the positive result is due to contamination with maternal antibody. IgA antibodies in adults may persist for months or years following acute infection. IgM-ELISA, IgM-ISAGA, IgA-ELISA, IgE, PCR: These tests were developed and their performance characteristics determined by the Toxoplasma Serology Laboratory, Palo Alto Medical Foundation. They have not been cleared or approved by the US Food and Drug Administration (FDA). However, approval by the FDA is not required for use of these tests by our reference laboratory.
Methodology	Neutralization, ISAGA, ELISA
Performing Site	Palo Alto Research Institute
CPU Mappings	**Result Code** / **Result Name** 113782 / Dye Test 113783 / IgM-ISAGA 113784 / IgA-ELISA

Toxoplasmosis Pregnancy Panel (> 16 weeks)	
Effective Date	**3/13/2012**
Test Code	S52569
CPT Codes	86406 X 2, 86777, 86778
Specimen Requirements	2.0 mL (0.5 mL) Serum Red Top Tube
Reject Criteria	ICTERIC, HEMOLYSIS , LIPEMIC, BACTERIALLY CONTAMINATED SPECIMENS

Instructions	INCLUDE PATIENT'S DATE OF BIRTH ON TEST REQUEST FORM. PLEASE CENTRIFUGE THE SPECIMEN. SEND SERUM ONLY. THE PATIENT'S NAME AND COLLECTION DATE MUST APPEAR ON THE SPECIMEN LABEL. UNLABELED SPECIMENS WILL NOT BE TESTED. HISTORY OF PATIENT IS REQUIRED FOR THE PROPER INTERPRETATION OF RESULTS. SUBMIT ALONG WITH THE SPECIMEN ANY HISTORY OF THE FOLLOWING: EYE FINDINGS; NORMAL NEUROLOGICAL FINDINGS; NORMAL BRAIN CALCIFICATION; ULTRASOUND; CT SCAN; TRANSFUSION HISTORY (DATES AND TYPES); HYDROCEPHALY (VENTRICULOMEGALY); CEREBRAL SPINAL FLUID RESULTS: CELL COUNT; GLUCOSE; PROTEIN. IT IS SUGGESTED THAT A MATERNAL SERUM SPECIMEN BE SUBMITTED ALONG WITH THE INFANT SPECIMEN SHOULD ADDITIONAL TESTING BE REQUIRED. THIS WILL BE PERFORMED AT AN ADDITIONAL CHARGE. CONTACT CLIENT SERVICES FOR CHARGES.
Transport Temperature	Room temperature
Specimen Stability	Room Temperature: 7 days Refrigerated: 14 days Frozen: Indefinitely
Set-up/Analytic Time	Set up: Tue, Thur; Report Available: 2-3 days
Reference Range	See laboratory report.
Always Message	If you have questions regarding these results, please telephone our consulting physicians at (650) 853-4828. The Sabin-Feldman Dye Test: measures primarily IgG antibodies. Any titer is considered positive. Serum is tested at a 1:16 dilution unless we are notified that patient has eye disease, in which case serum is tested undiluted. IgM-ELISA: (serum) negative 0.0-1.6, equivocal 1.7-1.9, >=2.0 positive; (CSF) negative 0.0 - 0.3; positive >=0.4. A negative IgM-ELISA result in an immunologically normal adult almost always excludes recent infection. IgM antibodies may persist for one year or longer following acute infection. IgA-ELISA: (adults) negative 0.0-1.4, equivocal 1.5-2.0, positive >=2.1; (infants < 6 months) negative 0.0-0.9, positive >=1.0. The IgA-ELISA appears to be a more sensitive test for detection of infection in the fetus and newborn than IgM. Both tests should be performed. If the IgA result on serum obtained within the first days of life is positive, the test should be repeated on serum collection ten days after birth to exclude the possibility that the positive result is due to contamination with maternal antibody. IgA antibodies in adults may persist for months or years following acute infection. IgE: Results should only be interpreted along with other serological data. Although IgE antibodies may persist for many months, their presence generally reflects a more acute phase of infection. Absence of detectable IgE antibodies does not exclude the possibility of acute infection. AC/HS: "Non-acute pattern" generally excludes recent infection. "Acute Pattern" may reflect recently acquired infection, but can persist for months or years following acute infection. An "equivocal pattern" may be associated with an infection acquired months earlier or in the distant past. A "non-reactive pattern" is observed in sera that are negative in the Toxoplasma Serological Profile. A "non-reactive pattern" may also be observed very early following infection (when the IgM test is generally positive), and when infection occurred in the more distant past. AC/HS results should only be interpreted with results of other tests in the Toxoplasma Serologic Profile. IgG Avidity: A high result in the first 16 weeks of gestation essentially excludes acute infection having been acquired during gestation. A low or equivocal IgG avidity result cannot be interpreted to mean that the patient has had a recently acquired infection since low avidity antibodies may persist for more than five months. IgG avidity results should only be interpreted with results of other tests in the Toxoplasma Serologic Panel. Interpretation can be altered if the patient has previously received anti-toxoplasma therapy, since this will affect IgG maturation kinetics during infection. IgG avidity is an investigational test. IgM-ELISA, IgM-ISAGA, IgA-ELISA, IgE, PCR: These tests were developed and their performance characteristics determined by the Toxoplasma Serology Laboratory, Palo Alto Medical Foundation. They have not been cleared or approved by the US Food and Drug Administration (FDA). However, approval by the FDA is not required for use of these tests by our reference laboratory.
Methodology	Neutralization, ELISA, Differential Agglutination
Performing Site	Palo Alto Research Institute
CPU Mappings	**Result Code** / **Result Name** 113785 / Dye Test 113786 / IgM-ELISA

113787	AC/HS

Toxoplasmosis Pregnancy Panel with Avidity (<16 weeks)	
Effective Date	**3/13/2012**
Test Code	S52570
CPT Codes	86777, 86778, 86777-59
Specimen Requirements	2.0 mL (0.5 mL) Serum Red Top Tube
Reject Criteria	ICTERIC, HEMOLYSIS , LIPEMIC, BACTERIALLY CONTAMINATED SPECIMENS
Instructions	INCLUDE PATIENT'S DATE OF BIRTH ON TEST REQUEST FORM. PLEASE CENTRIFUGE THE SPECIMEN. SEND SERUM ONLY. THE PATIENT'S NAME AND COLLECTION DATE MUST APPEAR ON THE SPECIMEN LABEL. UNLABELED SPECIMENS WILL NOT BE TESTED. HISTORY OF PATIENT IS REQUIRED FOR THE PROPER INTERPRETATION OF RESULTS. SUBMIT ALONG WITH THE SPECIMEN ANY HISTORY OF THE FOLLOWING: EYE FINDINGS; NORMAL NEUROLOGICAL FINDINGS; NORMAL BRAIN CALCIFICATION; ULTRASOUND; CT SCAN; TRANSFUSION HISTORY (DATES AND TYPES); HYDROCEPHALY (VENTRICULOMEGALY); CEREBRAL SPINAL FLUID RESULTS: CELL COUNT; GLUCOSE; PROTEIN. IT IS SUGGESTED THAT A MATERNAL SERUM SPECIMEN BE SUBMITTED ALONG WITH THE INFANT SPECIMEN SHOULD ADDITIONAL TESTING BE REQUIRED. THIS WILL BE PERFORMED AT AN ADDITIONAL CHARGE. CONTACT CLIENT SERVICES FOR CHARGES.
Transport Temperature	Room temperature
Specimen Stability	Room Temperature: 7 days Refrigerated: 14 days Frozen: Indefinitely
Set-up/Analytic Time	Set up: Tue, Thur; Report Available: 2-3 days
Reference Range	See laboratory report.
Always Message	If you have questions regarding these results, please telephone our consulting physicians at (650) 853-4828. The Sabin-Feldman Dye Test: measures primarily IgG antibodies. Any titer is considered positive. Serum is tested at a 1:16 dilution unless we are notified that patient has eye disease, in which case serum is tested undiluted. IgM-ELISA: (serum) negative 0.0-1.6, equivocal 1.7-1.9, >=2.0 positive; (CSF) negative 0.0 - 0.3; positive >=0.4. A negative IgM-ELISA result in an immunologically normal adult almost always excludes recent infection. IgM antibodies may persist for one year or longer following acute infection. IgA-ELISA: (adults) negative 0.0-1.4, equivocal 1.5-2.0, positive >=2.1; (infants < 6 months) negative 0.0-0.9, positive >=1.0. The IgA-ELISA appears to be a more sensitive test for detection of infection in the fetus and newborn than IgM. Both tests should be performed. If the IgA result on serum obtained within the first days of life is positive, the test should be repeated on serum collection ten days after birth to exclude the possibility that the positive result is due to contamination with maternal antibody. IgA antibodies in adults may persist for months or years following acute infection. IgE: Results should only be interpreted along with other serological data. Although IgE antibodies may persist for many months, their presence generally reflects a more acute phase of infection. Absence of detectable IgE antibodies does not exclude the possibility of acute infection. AC/HS: "Non-acute pattern" generally excludes recent infection. "Acute Pattern" may reflect recently acquired infection, but can persist for months or years following acute infection. An "equivocal pattern" may be associated with an infection acquired months earlier or in the distant past. A "non-reactive pattern" is observed in sera that are negative in the Toxoplasma Serological Profile. A "non-reactive pattern" may also be observed very early following infection (when the IgM test is generally positive), and when infection occurred in the more distant past. AC/HS results should only be interpreted with results of other tests in the Toxoplasma Serologic Profile. IgG Avidity: A high result in the first 16 weeks of gestation essentially excludes acute infection having been acquired during gestation. A low or equivocal IgG avidity result cannot be interpreted to mean that the patient has had a recently acquired infection since low avidity antibodies may persist for more than five months. IgG avidity results should only be interpreted with results of other tests in the Toxoplasma Serologic Panel. Interpretation can be altered if the patient has previously received anti-toxoplasma therapy, since this will affect IgG maturation kinetics during infection. IgG avidity is

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<tr><td>Methodology</td><td>Neutralization, ELISA, Avidity</td></tr>
<tr><td>Performing Site</td><td>Palo Alto Research Institute</td></tr>
<tr><td>CPU Mappings</td><td>
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<tr><td>113789</td><td>IgM-ELISA</td></tr>
<tr><td>113790</td><td>IgG Avidity</td></tr>
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